

which corresponds to “low level”, “medium level”, or “high level” indications. In some embodiments, apparatus 10 includes a label that illustrates the color-coding scheme, and an operator may compare the resulting color in window 36 with the label. In other embodiments, the color change cannot be detected with a human eye, and a machine or electronic reader, such as a spectrometer, is used to detect the color change. In alternate embodiments, other testing devices may be used. For example, apparatus 10 may incorporate a testing device whose indicium of a test result is characterized by a pH change, or some other change in the characteristic of the medium being analyzed.

[0060] After second fluid 25 and the result of the reagent/analyte reaction flow into third fluid reservoir 28, second fluid 25 and the result of the reagent/analyte reaction flow into channel 32 and contact testing device 30. After sufficient time to allow any remaining reagent (i.e., the reagent that has not reacted with the analyte) to react with testing device 30, a user may read the test result in window 36. The reaction time depends upon many factors, including the type of analyte and/or reagent. In the exemplary embodiment, the colorimetric sensor (i.e., testing device 30) is viewable through window 36. An operator (or machine) may then read a test result through window 36. Alternatively, window 36 may be positioned anywhere on apparatus 10.

[0061] FIG. 3 is a side view of apparatus 10, where valve 14 has been removed. First pathway 17 is positioned between first housing segment 16 and central housing segment 15; second pathway 19 is positioned between second housing segment 18 and central housing segment 15; third pathway 21 is positioned between third housing segment 20 and central housing segment 15; and fourth pathway 23 is positioned between fourth housing segment 22 and central housing segment 15. Each pathway 17, 19, 20, and 21 fluidically connects its respective housing segment 16, 18, 20, and 22 with central housing segment 15. Valve 14 (shown in FIG. 1) may be used to selectively close off any one of pathways 17, 19, 20, and 21.

[0062] In FIG. 3, frame 12 has a valve mounting feature 38 (such as an opening or mounting knob) for mounting valve 14 to frame 12. Valve 14 includes a feature that corresponds to the shape and size of feature 38 and valve 14 and knob 38 mate in order to attach valve 14 to frame 12. As seen in FIGS. 6B and 6C, valve 14 includes or is attached to rotate around a shaft 45 which extends from a back side 47 of frame 12. A stiffening washer 49 is also provided on back side 47 of frame 12. Washer 49 is sized to extend opposite the sealing portions of valve 14 (e.g., actuating ribs 4) to further stiffen the frame 12 adjacent flow restrictor locations 117, 119, 121 and 123 and aid in forming uniform seal forces. Washer 49 may be formed from a suitable stiffener such as cardboard, plastic (e.g., polycarbonate) or metal. A fastener (not shown) such as a Tinnerman style nut may be used to attach the valve 14 and shaft 45 relative to the frame 12. Bias of valve 14 toward a top side 51 of frame 12 may be achieved by placement of a wave washer (not shown) between the Tinnerman style nut (not shown) and the washer 49. Any suitable arrangement for rotatably mounting valve 14 to frame 12, while biasing valve 14 towards top side 51 of frame 12, will suffice.

[0063] Stops 40 and 42 as shown in FIG. 3 are also attached to frame 12 and project therefrom. Stops 40 and 42 help to prevent valve 14 from turning past a predetermined point. Specifically, if valve is rotated in a certain direction, stops 40 and/or 42 engage with a portion of valve 14 and prevent valve 14 from rotating further in that direction. If valve 14 had a

360-degree range of motion, an operator may unintentionally and accidentally open and close different flow paths through central housing segment 15.

[0064] As previously mentioned, in alternate embodiments, the sample preparation position of valve 14 may comprise two or more positions. In one embodiment, valve 14 includes first and second sample preparation positions. In the first sample preparation orientation, valve 14 closes off pathways 19, 21, and 23 between central housing segment 15 and second, third, and fourth housing segments 18, 20, and 22, respectively. This opens up flow path 17 between first housing segment 16 and central housing segment 15. The first sample preparation position allows the eluted sample to sit within central housing segment rather than flowing directly through central housing segment 15. An apparatus operator then has the option of releasing the eluted sample from central housing segment 15 after a sufficient time to allow capture medium 24 to capture the analyte from the eluted sample and/or for the analyte to react with a reagent. In the second sample preparation position, valve 14 closes off pathways 17, 19, and 23 between central housing segment 15 and first, second, and fourth housing segments 16, 18, and 22, respectively. This opens up flow path 21 between third housing segment 20 and central housing segment 15, and the eluted sample (minus the captured analyte) may be released from central housing segment 15.

[0065] In another embodiment, which may be combined with the embodiment having two sample preparation positions, valve 14 includes first and second testing positions. In the first testing position, valve 14 closes off pathways 17, 19, and 21 between central housing segment 15 and first, second, and third housing segments 16, 18, and 20, respectively. As a result, pathway 23 is the only open pathway from central housing segment 15. The first testing position allows the second buffer 25 (retained in fourth housing segment 22) to sit within central housing segment 15. If a reagent material is disposed in fourth housing segment 22, fourth pathway 23, or central housing segment 15, the option of having a first testing position allows an operator to control the amount time in which the analyte and reagent may react. In the second testing position, valve 14 closes off pathways 17, 21, and 23 between first, third, and fourth housing segments 16, 20, and 22, respectively. Pathway 19 is then the only open pathway from central housing segment 15, and any fluid contained within central housing segment 15 may be released to contact testing device 30. The second testing position allows the operator to control when to allow the analyte and reagent to contact testing device 30. Of course, in both the first and second testing positions, valve 14 does not necessarily need to close pathway 17 because if apparatus 10 is positioned so that gravity flows in direction g, fluid will not likely flow up pathway 17.

[0066] Other valve 14 positions are also contemplated. Valve 14 positions depend upon many factors, including the number of housing segments and the type of assay being used to detect the analyte.

[0067] The present invention may also be a molded or otherwise fabricated device that includes rigid housing segments and other fluid control components. The flow paths between the central housing and housing segments may be formed of existing tubing components, which incorporate alternate valve arrangements to control fluid flow. The operation of the molded device is similar to apparatus 10 described in reference to FIGS. 1 and 2.